

## UNITED STATES DEPARTMENT OF COMMERCE **Patent and Trademark Office**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR		ATTORNEY DOCKET NO.
08/894,73	3 08/27/	97 GENTILE	М	970845
_	HM42/0327 ARMSTRONG, WESTERMAN, HATTORI, MCLELAND & NAUGHTON			EXAMINER
				iCK,P
1725 K ST	REET NORTH	WEST	ART UNIT	PAPER NUMBER
SUITE 100 WASHINGTO	) N DC 20006		1614	3
			DATE MAILED:	03/27/98

Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trademarks** 

Application No. 08/894,733 Applicant(s)

Gentile et al.

Office Action Summary

Examiner

Phyllis G. Spivack

Group Art Unit 1614



Responsive to communication(s) filed on	·
This action is <b>FINAL</b> .	
Since this application is in condition for allowance except for formal in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 1	1, 400 0.0. 210.
shortened statutory period for response to this action is set to expire longer, from the mailing date of this communication. Failure to respondication to become abandoned. (35 U.S.C. § 133). Extensions of the CFR 1.136(a).	
sposition of Claims	intere ponding in the application
	is/are pending in the application.
Of the above, claim(s)	is/are withdrawn from consideration.
Claim(s)	is/are allowed.
XI Claim(s) 1-10	is/are rejected.
Claim(s)	is/are objected to.
☐ Claims ar	re subject to restriction or election requirement.
□ See the attached Notice of Draftsperson's Patent Drawing Revieur □ The drawing(s) filed on	ty the Examiner.  is approved disapproved.  35 U.S.C. § 119(a)-(d).  riority documents have been
*Certified copies not received:  Acknowledgement is made of a claim for domestic priority under  Attachment(s)  Notice of References Cited, PTO-892 — DOM Whies Market PTO-1449, Paper No(s).  Information Disclosure Statement(s), PTO-1449, Paper No(s).  Interview Summary, PTO-413  Notice of Draftsperson's Patent Drawing Review, PTO-948  Notice of Informal Patent Application, PTO-152	er 35 U.S.C. § 119(e).
SFF OFFICE ACTION ON THE FO	OLLOWING PAGES

Office Action Summary

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Art Unit: 1205

Applicants are urged to file an Information Disclosure Statement if there are references deemed pertinent to the prosecution of the present application.

Claims 1-10 are under consideration.

The disclosure is objected to for the following informalities: The recitation in claim 1 "characterized by the fact that it contains" may more properly be stated as simply "comprising".

The term "property" on line 3 should be plural. Appropriate correction is suggested.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bosone et al., WO 94/20449.

Bosone teaches pharmaceutical compositions suitable for parenteral administration, having anti-inflammatory and analgesic properties, wherein an alkylammonium salt of the 2-arylpropionic acid, ketoprofen, in racemic as well as enantiomeric form, is disclosed. Salts with an achiral or chiral organic base, such as lysine, dropropizine and tromethamine, are depicted. See, in particular, Examples 1-3 and 5-8. Further, a process for the preparation of pharmaceutical compositions is disclosed on pages 9-10. The claims differ in that 2-arylpropionic acid compounds other than ketoprofen, such as ibuprofen, naproxen and tiaprofenic acid, are not

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disclosed. Further, Bosone does not specifically state an osmolarity range, a pH range, the absence of preservatives and supporting substances nor a requirement for a gas-inert atmosphere. However, one having ordinary skill in the art would have been motivated to prepare pharmaceutical compositions suitable for parenteral administration, having anti-inflammatory and analgesic properties, comprising 2-arylpropionic acid compounds other than ketoprofen, in view of the teachings of Bosone. Such modification would have been obvious in the absence of evidence to the contrary because ketoprofen, ibuprofen, naproxen and tiaprofenic acid are all well established in the art as 2-arylpropionic acid compounds of very close structural similarity and pharmacological activity. It would have been reasonable to expect these recited compounds to exhibit the same physical and chemical properties in a pharmaceutical composition. Further, the selections of optimal conditions for the preparation of pharmaceutical compositions with respect to atmosphere, the pH, the osmolarity and the presence or absence of excipients as preservatives and supporting substances, are parameters well within the purview of those skilled in the art of formulation chemistry through no more than routine experimentation.

No claim is allowed.

Any inquiry concerning this communication should be directed to Phyllis Spivack at telephone number (703) 308-4703.

March 24, 1998

PHYLLIS SPIVACK PRIMARY EXAMINER

Phyllis Spiract